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10/696,381

10/28/2003

Albert K. Chin

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/696,381 | Applicant(s) CHIN, ALBERT K. | |
| | Examiner PHILIP R. SMITH | Art Unit 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- [01] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/14/09 has been entered.

Claim Rejections - 35 USC § 103

- [02] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [03] Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789) and in further view of Vandegrift (2,201,749).
- [04] With regard to claim 1:

[04a] Horzewski discloses an apparatus for performing a surgical procedure in tissue comprising:

- an inner cannula ("dilator 150" 12/49) having an elongated body and a tip ("bulbous region 127" 12/64) that is positioned at a distal end of the elongated body and that is configured to dissect tissue ("dilator 150 contains a guidewire channel 122" 12/49); and
- an outer expandable sheath ("side arm sheath 90" 11/67) disposed about the inner cannula and disposed to contact tissue and configured to expand in an outward direction against tissue in contact therewith ("accommodate positive radial expansion

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over a specific range of radial dimensions" 12/7-9) responsive to the tip of the inner cannula slidably passing longitudinally through the sheath in a proximal direction through the sheath for removal therefrom ("Withdrawal of the dilator [150], however, through the confines of the sheath, increases the profile of the delivery channel to the desired profile as bulbous region 127 is withdrawn through the shaft" 13/12-15).

[04b] Horzewski does not disclose:

- That the outer expandable sheath comprises first and second shells.

[04c] Gibson discloses:

- an outer expandable sheath ("tube A" 1/28) configured to expand in an outward direction responsive to the tip of an element ("rod D" having "plunger D2" 2/65) slidably passing longitudinally through the sheath (2/71-89). Gibson further discloses that the outer expandable sheath comprises a first shell and a second shell ("segmental bars e'," 2/60-70) adjacently aligned along longitudinal edges thereof.
- a resilient connector ("thin soft rubber sheath C," 2/81) attached between the first and second shells for resiliently urging a distal end of the first shell toward a distal end of the second shell (a point indicated by "a2" in the figures) to form an inner dimension at the distal end of the outer expandable sheath smaller than the outer dimension of the tip positioned distally of the distal end of the outer expandable sheath.
- At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the outer expandable sheath having resiliently connected first and second shells disclosed by Gibson be substituted for the outer expandable sheath disclosed by Horzewski. It is obvious to substitute one known element for another to obtain

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predictable results. Radially expansive tubes are known in the art, as are radially expansive shells. A skilled artisan could have substituted one for the other, and the resulting substitution would have been predictable.

[04d] Horzewski in view of Gibson does not disclose:

- that the first and second shells are configured as substantially half cylindrical segments. Instead, Gibson discloses "segmental bars" which are adjacently aligned along the longitudinal edges thereof. Figure 3 shows five such "segmental bars".

[04e] Vandegrift discloses:

- an expanding vein tube which is "split vertically throughout the greater portion of its length along diametrically opposed lines as at 2,2 which provide semi-circular legs 3 and 4" (1/51-54). The tube disclosed by Vandegrift accomplishes a similar function to that of Horzewski in view of Gibson: expansion of an outer shell in response to a "plunger" or "dilator" being passed through it.
- At the time of the invention, it would have been obvious to a person of ordinary skill in the art that an outer shell having two half cylindrical segments configured to expand in response to a dilator ("3 and 4" as disclosed by Vandegrift) be substituted for the outer shell having five "segmental bars" which are configured to expand in response to a dilator (as disclosed by Horzewski in view of Gibson). A skilled artisan would be motivated to do so in order to provide for simpler manufacturing of the device, and fewer longitudinal slits with which to potentially injure the patient.

Additional Claim Rejections - 35 USC § 103

[05] Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789) and Vandegrift (2,201,749), and in further view of Lehrer (5,685,856).

[06] With regard to claim 14:

[06a] Horzewski in view of Gibson and Vandegrift discloses an elongated handle ("side arm 46" see Figure 3C), as noted above.

[06b] Horzewski in view of Gibson and Vandegrift does not disclose that the handle was eccentrically attached near a proximal end of the outer sheath and displaced laterally substantially in said outward direction.

[06c] Lehrer discloses in 12/51-58 (see Figures 1A and 3A) a "handle 120" wherein:

Handle offset 118 offsets handle 120 to the side of sleeve guide 104 and is adjustable via knob 122 to vary the distance between distal handle end 124 and the distal tip of sleeve guide 104. By adjusting knob 122, the surgeon can vary the depth of penetration of the device into the body cavity by holding the handle at the distal end and against the surface of the abdominal wall. An advantage of this procedure is that accidental injuries due to over penetration can be avoided.

[06d] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to provide the handle disclosed by Lehrer on the apparatus disclosed by Horzewski in view of Gibson and Vandegrift. A skilled artisan would be motivated to do so in order to avoid "accidental injuries due to over penetration," as noted above.

Response to Arguments

[07] Applicant's arguments with regard to claim 1 have been fully considered but they are not persuasive. Applicant contends that "the structure of Gibson '789 is not noted to permit removal of

the inner cannula from the outer expandable sheath (to provide an available instrument channel)."

The same argument is made with respect to Vandegrift.

[07a] However, Horzewski, the disclosure upon which the combination is based, does disclose removal of an inner cannula from an outer expandable sheath.

[07b] Applicant has failed to show that Horzewski does not permit removal. Nor that the segmental bars and rubber sheath of Gibson would not permit removal if incorporated into the out expandable sheath disclosed by Horzewski. Nor that the half-cylindrical shells of Vandegrift would not permit removal if incorporated into the out expandable sheath disclosed by Horzewski in view of Gibson.

[08] Applicant's arguments with regard to claim 14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

[09] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

[10] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.

[11] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/

Examiner, Art Unit 3739

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739